



**Bio-Rad
Laboratories**

ECS Division
3726 E. Miraloma Avenue
Anaheim, CA 92806
Telephone (714) 630-6400
Toll Free (800) 854-6737

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510(k) Summary

Submitter

Bio-Rad Laboratories, ECS Division
3726 E. Miraloma Avenue
Anaheim, CA 92806
(714)630-6400
Fax (714)666-1383

Contact Person

Elizabeth Platt

Date of Summary Preparation

November 27, 1996

Device (Trade & Common Name)

Lyphochek Coagulation Control

Classification Name

Class II, 81GGN
CFR 864.5425: Plasma Coagulation Control

Devices to Which Substantial Equivalence is Claimed

ThromboScreen Coagulation Control Plasma
Pacific Hemostasis
K820450

Statement of Intended Use

Lyphochek Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems.



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Description of the Device

Lyphocheck Coagulation Control is prepared from human plasma with added constituents of non-human origin and purified biochemicals. The control is provided in lyophilized form for increased stability.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the similarities between the Bio-Rad Lyphocheck Coagulation Control and the devices to which substantial equivalence is claimed.

	Bio-Rad Lyphocheck Coagulation Control	Pacific Hemostasis ThromboScreen Coagulation Control Plasma
Intended Use	A quality control plasma to monitor the precision of citrated coagulation systems.	A control in prothrombin time and partial thromboplastin time determinations
Form	Lyophilized	Lyophilized
Matrix	Human plasma	Human Plasma
Storage	2 - 8°C	2 - 8°C
Open Vial Claim	16 hours at 2-25°C	8 hours at 2-8°C
Levels	Level 1, 2 and 3	Level 1, 2 and 3
Assays	prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (Level 1)	prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (Level 1)